IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
***ex rel.* JOHN UNDERWOOD,**	)	
	)	**CIVIL ACTION NO. 03-3983**
Plaintiff,	)	
	)	
vs.	)	**Judge Paul S. Diamond**
	)	
GENENTECH, INC., et. al.,	)	
	)	
Defendants.	)	
	)	
	)	

ORDER

Upon consideration of the Motion of Defendant Genentech, Inc., to Dismiss Relator John Underwood's Second Amended Complaint, IT IS HEREBY ORDERED that the motion is GRANTED and the Second Amended Complaint is dismissed with prejudice.

BY THE COURT:

____
Diamond, J.

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UNITED STATES OF AMERICA *ex rel.* **JOHN UNDERWOOD,**	)	
	)	**CIVIL ACTION NO. 03-3983**
Plaintiff,	)	
vs.	)	**Judge Paul S. Diamond**
GENENTECH, INC., et. al.,	)	
Defendants.	)	

MOTION OF GENENTECH, INC., TO
DISMISS RELATOR JOHN UNDERWOOD'S
SECOND AMENDED COMPLAINT

Defendant Genentech, Inc. ("Genentech") respectfully moves the Court to dismiss relator John Underwood's Second Amended Complaint for failure to state a claim upon which relief can be granted, pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

The attached memorandum is incorporated by reference.

Dated June 23, 2010

Respectfully submitted,

GENENTECH, INC.

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MEMORANDUM IN SUPPORT OF GENENTECH, INC.'S MOTION TO DISMISS RELATOR JOHN UNDERWOOD'S SECOND AMENDED COMPLAINT

Defendant Genentech, Inc. ("Genentech") respectfully submits this Memorandum of Law in Support of its Motion to Dismiss the Second Amended Complaint (the "SAC") of relator John Underwood ("Relator") pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

For six years, the Government investigated whether Genentech violated either the Federal Food, Drug, and Cosmetic Act ("FDCA") or the Anti-Kickback statute ("AKS") in connection with its promotion of Rituxan. The Government ultimately determined *not* to indict the company for violations of either of these criminal statutes. Despite the Government's decision, Relator now seeks to impose civil liability on the company for its conduct but, because neither the FDCA nor the AKS authorizes a private right of action, he advances a claim under a different statute, the civil False Claims Act ("FCA"), which the Government also declined to prosecute. Specifically, he alleges that Genentech violated both the FDCA (by promoting Rituxan for uses not yet approved by the Food and Drug Administration) and the AKS (by providing unlawful remuneration to physicians) and then, switching statutory horses, he pleads that the company thereby caused the submission of "fraudulent" claims to the Government in violation of the FCA.

Both of Relator's claims should be dismissed with prejudice for the fundamental reason that they do not, and cannot, connect the alleged violations of the FDCA and the AKS to violations of the False Claims Act. The FDCA prohibits manufacturers from making certain statements about the safety and efficacy of their drugs. The AKS prohibits manufacturers from offering or paying remuneration to physicians to induce them to purchase or prescribe products. Neither statute addresses the issue of claims for reimbursement to the Government. The FCA, on the other hand, is concerned exclusively with claims for reimbursement. There are no links between the statutes.

This fundamental disconnect is reflected in Relator's pleadings. Count I, relating to alleged off-label promotion, contains no allegation that Genentech *fraudulently* violated the FDCA or that the Government would not have reimbursed physicians for the off-label uses at issue. It thus fails to state a cognizable FCA claim because it does not adequately allege that any claims for reimbursement submitted by physicians were "false or fraudulent," that Genentech "caused" any physicians to submit false or fraudulent claims for reimbursement to the Government, or that Genentech's alleged conduct was "material" to any Government payment decision. Count II, about alleged kickbacks, likewise fails adequately to allege the "false or fraudulent" element or other elements of a FCA claim.[1]

The deficiencies in the SAC are, at one level, formal: Relator literally fails to allege all the elements of a cognizable claim under either count, which itself renders both counts deficient. But the deficiencies are also fundamental: particularly because of the uniquely broad reimbursement rules governing oncology drugs, Relator *cannot* connect the alleged violations of the FDCA and the AKS to a violation of the FCA. Indeed, the majority of courts have not allowed cases such as this one to proceed past the pleadings stage, and no FCA claim alleging the off-label promotion of an oncology medicine has been permitted to proceed past the pleadings stage. For this reason, the deficiencies in the SAC are irremediable, and it should be dismissed with prejudice.

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[1] For the reasons set forth in Section III, to the extent pled, these pleadings are also insufficiently particular under Rule 9(b), especially as to a new claim that Genentech unlawfully promoted Rituxan for treatment of Rheumatoid Arthritis.

FACTUAL BACKGROUND

A. Clinical Background

1. Nature And Effectiveness Of Rituxan

Rituxan was the first monoclonal antibody ever approved for the treatment of disease in humans and is generally recognized to be the most important breakthrough in the treatment of cancer over at least the past decade. Rituxan received FDA approval in 1997 for the treatment of a particular form of lymphoma – relapsed or refractory low-grade or follicular CD-20+ non-Hodgkins lymphoma ("NHL"). (Amended Complaint ¶ 13.) Rituxan was subsequently determined to be safe and effective in additional dosing regimens and disease states and received additional FDA approvals for other dosing regimens,[2] other stages and forms of lymphoma,[3] Chronic Lymphocytic Leukemia,[4] and Rheumatoid Arthritis.[5] These approvals were based on clinical trials whose results were announced and/or published in the medical literature – and thus available to clinicians – well before the respective FDA approvals.[6]

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[2] Alternative dosing regimens were approved in April 2001 and September 2006. Where, as here, there is no dispute as to the authenticity of information or materials, the Court properly may consider them on a motion to dismiss. In particular, the Third Circuit and district courts within the Third Circuit have taken judicial notice of FDA materials. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of the FDA's Center for Drug Evaluation and Research's Listing of New & Generic Drug Approvals in deciding a motion to dismiss). With the exception of the material attached to the Welsh Declaration, all of the materials offered for judicial notice are for the Court's background and are not being offered as a basis for any aspect of the Court's decision.

[3] Specifically, Rituxan was approved, in combination with various other drugs, for the front-line treatment of low-grade CD20-positive NHL and for the front-line treatment of aggressive CD20-positive NHL in 2006. *See* Rituxan Labeling at 3 (2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103705s5311lbl.pdf.

[4] Rituxan was approved for the treatment of patients with previously untreated and previously treated CD20-positive Chronic Lymphocytic Lymphoma ("CLL"). *Id.*

[5] In 2006, Rituxan was approved in combination with various other drugs to reduce signs and symptoms of adult patients with moderately-to-severely active Rheumatoid Arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. In 200, Rituxan was approved in combination with various other drugs for slowing the progression of structural damage in adult patients with moderately-to-severely active Rheumatoid Arthritis. *Id*.

2. Off-Label Prescribing Of Rituxan

As Relator concedes, and as the FDA has recognized, "healthcare professionals may lawfully use or prescribe [an approved drug] for uses or treatment regimens that are not included in the product's approved labeling. . . . These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care."[7] Off-label prescribing is particularly pervasive in oncology, in part because oncologists and their patients face different risk/benefit calculations than other physicians and patients: the consequences of *not* taking medication that turns out to be effective in treating cancer are obviously far starker than the consequences of taking a medication that proves not to be effective. Consistent with this broader pattern of care, physicians lawfully prescribed Rituxan "off-label" for various stages and forms of lymphoma and leukemia well before the FDA approved the drug for those uses. Several studies of these off-label uses concluded that patients treated off-label had better overall survival rates.[8]

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[6] *See id*. at 20-24; *see also* Robert Marcus et al., *CVP chemotherapy plus rituximab compared with CVP as first-line treatment for advanced follicular lymphoma*, 105 Blood 1417 (2005); Bertrand Coiffier et al., *CHOP Chemotherapy Plus Rituximab Compared With CHOP Alone in Elderly Patients With Diffuse Large-B-Cell Lymphoma*, 346 New England J Med. 235 (2002).

[7] FDA, Office of the Comm'r, Office of Policy, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), *available at* http://www.fda.gov/oc/op/goodreprint.html ("*Reprints Guidance*"). *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 & n.5 (2001) (noting that some off-label uses are "generally accepted" and citing materials advancing the proposition that off-label use often represents "optimal medical care").

[8] *See* Labeling, *supra* note 3, at 20-24; Rituximab Maintenance Therapy Dramatically Improves Survival For Patients With Lymphoma—Risk Of Death Can Be Halved, Medical News Today, Feb. 17, 2006 ("Two years of maintenance therapy with rituximab dramatically improves the

B. Reimbursement for Off-Label Uses of Rituxan

Genentech does not seek reimbursement from the Government for Rituxan. Rather, Genentech sells Rituxan to physicians who administer the drug to patients and subsequently seek reimbursement from either the Government (Medicare or Medicaid) or private insurers. Medicare covers all on "on-label" uses of the drug.[9] In addition, the Medicare program is *obligated* to reimburse physicians for oncology drugs prescribed for indications listed in certain specified compendia ("on-compendia uses").[10] Moreover, since 1993, when Congress determined specifically to expand coverage for cancer drugs, the Medicare statute also provides that the Medicare carriers – the local agents responsible for administering the Medicare program – *may* reimburse physicians even for *off*-compendial uses of oncology drugs based on authoritative medical literature or accepted standards of medical practice.[11] Under these rules,

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chances of survival for patients suffering from one of the most frequent forms of lymphoma, indolent non- Hodgkin's Lymphoma"); Holger Schulz et al., *Immunochemotherapy With Rituximab and Overall Survival in Patients With Indolent or Mantle Cell Lymphoma: A Systematic Review and Meta-analysis*, 99 J Nat'l Cancer Inst. 706, 712 (2007) (use of Rituxan in conjunction with chemotherapy "improves overall survival in patients with advanced-stage indolent and mantle cell lymphomas compared with chemotherapy alone.")

[9] *See* 42 U.S.C. § 1396r-8(k)(6).

[10] 42 U.S.C. § 1395x(t)(2)(B)(ii)(I). On-compendia uses are covered by Medicare unless the Secretary determines the use is not medically appropriate or the use is identified as "not indicated" in one or more of the enumerated compendia. *Id.* The Secretary has made no such determination with respect to Rituxan, and Rituxan, to our knowledge, has never been listed as "non-indicated" for any of the disease states at issue in this investigation in any compendium. Compendia, such as the United States Pharmacopeia, are standards-setting authorities that publish comprehensive and authoritative evaluations of marketed medications. *See, e.g.*, http://www.usp.org/.

[11] *See* 42 U.S.C. § 1395x(t)(2)(B)(ii)(II); Medicare Benefit Policy Manual, Ch. 15, § 50.4.5 (2010). The language giving carriers discretion to cover off-compendia uses of oncology drugs was added to the definition of "drugs and biologicals" as part of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13553(b), 107 Stat. 312, 591. The Conference Report for this provision states explicitly that Medicare coverage of an "anti-cancer chemotherapeutic regimen for a medically accepted indication" would "*not necessarily [be]*

during the period at issue, most uses of Rituxan were covered by Medicare either because they were on-label, because they were on-compendia,[12] or because authoritative literature and accepted standards of medical practice supported discretionary pre-compendial coverage by the Medicare carriers.[13]

C. Investigative And Procedural History

In response to a subpoena issued on October 3, 2004, Genentech produced over six million pages of documents to the Government, and the Government conducted an extensive investigation. In August 2008, the Criminal Division of the U.S. Attorney's Office for the Eastern District of Pennsylvania closed its criminal investigation and on October 20, 2009, after conducting additional factual inquiry, the Civil Division likewise declined to intervene in the FCA action brought by the Relator.

D. Relator's Complaints

The Original Complaint was filed on July 3, 2003 and unsealed in March 2010. The complaint purported to allege seven causes of action against Genentech and Roche Holdings,

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limited to the uses approved by the FDA as described on the label." H.R. Rep. No. 103-213, at 791 (1993) (Conf. Rep.) (emphasis added).

[12] Specifically, in addition to its various on-label indications, Rituxan received compendial coverage for CLL and Waldenstrom's Macroglobulinemia in September 2001; Immune Thrombocytopenic Purpura in July 2002; front-line aggressive, refractory aggressive, and front-line indolent NHL in November 2002; and reinduction (*i.e.*, maintenance) therapy for NHL in January 2004.

[13] Medicaid coverage for prescription drugs is quite similar. A state Medicaid program *must* cover any drug that is used for a purpose which is either (1) FDA approved, *or* (2) cited in at least one of several specific compendia. States may further elect to cover "off-compendia" uses as specified in their State Medicaid plans, statutes, regulations, or applicable state Medicaid guidance. *See* 42 U.S.C. § 1396a(54), 42 U.S.C. § 1396r-8(k)(2)(A), To our knowledge, none of these sources prohibited coverage of Rituxan for off-compendia uses.

Inc. The First Amended Complaint, filed on November 8, 2005 and unsealed on December 18, 2009, was largely identical to the Original Complaint. (*See generally*, Original Complaint ¶ 17).

Relator filed and prevailed upon a Motion For Leave To File A Second Amended Complaint and accordingly filed the SAC on April 15, 2010. The SAC contains just two counts: Count I alleges that Genentech caused the submission of false claims by promoting Rituxan for off-label uses in violation of the FDCA (SAC ¶¶ 53-55), and Count II alleges that the company caused the submission of false claims by paying kickbacks to certain oncologists who were members of "advisory boards" in violation of the AKS, (SAC ¶¶ 56-62). The SAC differs in numerous respects from the First Amended Complaint, *see* Redline Comparison of First Amended Complaint and Second Amended Complaint, attached to Welsh Decl. as Exhibit A, but there are two particularly material deletions and one material addition: the SAC *withdraws* the allegation that Genentech made false statements to physicians regarding Rituxan (as alleged in Count II of both prior complaints), it *withdraws* the allegation that the claims submitted by physicians were "false" (relying instead on a theory that they were "fraudulent"), and it *adds* the entirely new allegations that Genentech promoted Rituxan off-label to treat Rheumatoid Arthritis.

STANDARD OF REVIEW

In reviewing a motion to dismiss for failure to state a claim, a district court first must accept as true all well-pleaded allegations and draw all reasonable fact inferences in favor of the non-moving party, but it must disregard legal conclusions. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009); *Bd. of Trs. of Bricklayers Local 6 v. Wettlin Assocs. Inc.*, 237 F.3d 270, 272 (3d Cir. 2001). The court must then determine whether the complaint "set[s] forth a legally cognizable right, interest, or injury." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010).

ARGUMENT

To state a legally cognizable claim for relief under the FCA against a manufacturer, a relator must adequately plead that the defendant "knowingly . . . caus[ed] to be presented[] a false or fraudulent claim for payment." 31 U.S.C. § 3729(a).[14] All circuits to address the issue have also interposed a requirement that the alleged misconduct be "material" to the Government's decision to pay the claim. Relator has not satisfied his obligation to plead these elements of either count. For this fundamental reason, both counts must be dismissed.

I. COUNT ONE SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM.

Count I is defective for three reasons. First, Relator fails adequately to plead that any claims submitted by physicians for prescriptions of Rituxan for off-label uses were "false or fraudulent." Second, the SAC does not adequately plead that Genentech "caused" physicians to submit any false or fraudulent claims. And third, the SAC makes no allegation that any conduct by Genentech was material to any payment decision by the Government.

A. Relator Does Not Plead A Legally Cognizable False Claim.

Submission of a "false or fraudulent" claim for payment is the *sine qua non* of a FCA cause of action. *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005). The FCA does not define "false" or "fraudulent," and so courts have filled the gap. Virtually all courts recognize that a claim is "false" if it (1) contains a knowingly false statement or omission (*i.e.*, if it is false on its face), or (2) contains a false express certification (*i.e.*, if it contains a false certification that the goods or services were provided in compliance with a specific statutory or regulatory scheme). Some courts, though not the Third Circuit, have also recognized another category of "false" claims: claims that involve false "implied" certification of compliance with underlying statutes or regulations (*i.e.*, claims that are not facially false but "impliedly" certify that the goods or services were provided in compliance with a specific statutory or regulatory scheme). *See, e.g., Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 303-04 (3d Cir. 2008) (describing categories but declining to adopt or reject implied certification theory); *overruled on other grounds*, *United States ex rel. Eisenstein v. City of N.Y.*, 129 S. Ct. 2230 (2009); *Mikes v. Straus*, 274 F.3d 687, 696-700 (2d Cir. 2001) (describing three categories). Count I does not allege claims that are either facially false or that contain either sort of false certification and thus it fails the fundamental requirement that a complaint state a cognizable theory of liability.

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[14] On May 20, 2009, the False Claims Act was amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21. FERA made both technical and substantive changes to the FCA. However, with one exception that is inapplicable here, FERA's amendments are prospective only. *See Graham County Soil & Water Conserv. Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1408-09 n.17 (2010). Genentech refers throughout this motion to numbering and substantive provisions of the FCA as it existed prior to FERA's enactment.

1. The Complaint Does Not Allege That Any Claims Were "False" Under Any Of The Three Known Categories Of Falsity.

Relator does *not* allege that any physicians submitted claims to the Government that were "factually false" – *i.e.*, that any claims for Rituxan reimbursement contained false information. He does not, for example, allege that any physician, at Genentech's urging, lied about any patient's diagnosis or the nature of the treatment provided.[15]

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[15] The only theory of which we are aware that any court has held that a violation of the FDCA renders claims "false" is the theory that non-reimbursable claims are inherently false. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001). This Court need not address that theory here because Relator has not alleged that the claims at issue were not reimbursable and, in fact, they were. In any event, that theory is legally insupportable. *See, e.g., Horras v. Leavitt*, 495 F.3d 894 (8th Cir. 2007) (submission of presumptively non-reimbursable claims not unlawful if accurately described); *United States v. Calhoon*, 97 F.3d 518, 529 (11th Cir. 1996) (same); *United States ex rel. Burlbaw v. Orenduff*, 400 F. Supp. 2d

Relator also does not allege that any claims contained false "express certifications." Nor could he have done so. Claims for Rituxan were made on the CMS-1500 Form – the standard claim form used by non-institutional providers to bill Medicare and Medicaid for Rituxan treatments.[16] This form notably does *not* require certifications that usage was on-label, that the usage was reimbursable, or that the drug was prescribed in compliance with the Anti-Kickback statute.

Nor does Relator allege falsity under the "implied certification" theory. As a starting point, the Third Circuit expressly has declined to decide whether the "implied certification" theory of FCA liability is viable. *Our Lady of Lourdes Med. Ctr.*, 552 F.3d at 303-04. But even assuming that the Third Circuit *were to* endorse the "implied certification" theory (and it has always discussed the doctrine in the context of not adopting it), Relator *has not* and *could not* state a claim under this theory. According to the Third Circuit:

> To state a claim under [an implied certification] theory it is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but *also that payment of the federal funds was in some way conditioned on compliance with those regulations*. Otherwise, the False Claims Act would be turned into a 'blunt instrument to enforce compliance with all . . . regulations' rather than 'only those regulations that are a precondition to payment.'

Id. at 304 (internal citations omitted) (emphasis added) (omission in original); *see also United States ex rel. Lobel v. Express Scripts, Inc.*, 351 F. App'x 778, 780 (3d Cir. 2009) (implied

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1276, 1289 (D.N.M. 2005) ("It cannot be an actionable violation of the FCA for an individual to provide truthful information to the government, in order to allow the government to determine whether or not that information establishes eligibility for a certain program."), *aff'd*, 548 F.3d 931 (10th Cir. 2008); *United States ex rel. Pritsker v. Sodexho, Inc.*, 2009 WL 579380, at *16-17 (E.D. Pa. Mar. 6, 2009) (no FCA claim where government agency did not bar conduct), *aff'd on other grounds,* 2010 WL 438437 (3d Cir. Feb. 9, 2010), *petition for cert. filed*, No. 09-1519 (U.S. June 11, 2010); *United States ex rel. McDermott v. Genentech, Inc.*, 2006 WL 3741920, at *13 (D. Me. Dec. 14, 2006) (no false claim where off-label use is on-compendial).

[16] CMS-1500 Form has boxes in which to record a diagnosis code, also known as the ICD-9 code, and information about the treatment. *See* HCFA-1500 form, boxes 21, 22, & 24 (attached as Exhibit B to Welsh Decl.).

certification theory viable only where compliance with underlying statute is a "condition of payment");. *United States ex rel. Wilkins v. United Health Group, Inc.*, 2010 WL 1931134, at *6 (D.N.J. May 13, 2010) (implied certification is viable only when the underlying statute *expressly* states that payment is conditioned on compliance).

Here, Relator has not alleged any condition of payment that has been violated: indeed, he has not alleged that the payment of the federal funds at issue – Medicare payments to physicians for Rituxan – is conditioned on either the physician's or the manufacturer's compliance with any law or regulation. That alone is dispositive. But, more fundamentally, he could not have done so. No rule conditions Medicare reimbursement to on-label uses; no rule conditions payment on physicians' certification that the use for which they have prescribed a medication is reimbursable; and no rule conditions payment to *physicians* on compliance by *manufacturers* with the FDCA's rules governing "off-label promotion."

2. Relator's Allegation That Off-Label Claims Were "Fraudulent" Fails To State A FCA Claim.

Perhaps recognizing that his claim does not, and cannot, fit within any of the recognized categories of "false" claims, in the SAC Relator *deleted* the allegation that Genentech caused the submission of "false" claims and instead alleged that "claims were *fraudulent* in that Genentech intentionally influenced medical care providers to present them by engaging in an illegal pattern of conduct, *i.e.*, off-label marketing of a pharmaceutical product." (SAC ¶ 1 (emphasis added)); *see also* Decl. Welsh, Ex. A. This semantic shift does not salvage Count I both because it is logically and legally indistinct from the theory of "implied certification," and because Relator's allegation that off label marketing is a predicate "fraud" offense is legally incorrect and – as pled – factually insufficient.

a. The "Fraudulent Claims" Theory Is Indistinct From the "Implied Certification" Theory.

Relator's theory that a violation of the FDCA by Genentech renders claims by physicians for off-label uses "fraudulent" and therefore actionable under the FCA is a relatively novel theory of liability which has previously been advanced in "bid-rigging" and similar "fraud in the inducement" cases. Those cases involve the question of whether all claims submitted by an entity that has falsely gained eligibility to a government program are "fraudulent."[17] They are entirely distinguishable from this one, in which liability (if any) does not turn on Genentech's eligibility for any government program, but rather on whether physicians submitted individual false claims.

But Relator's "fraudulent claims" theory should be rejected not just because it is novel but rather because it adds nothing. The Third Circuit, like many others, has made clear that the FCA is not an all-purpose anti-fraud statute, *Our Lady of Lourdes Med. Ctr.*, 552 F.3d at 304, but it can be invoked as a remedy only in those circumstances in which the underlying violation of a statutory scheme necessarily renders subsequent related claims ineligible for payment – *i.e.*, only when there is an independent rule making payment of the claims at issue contingent on compliance with the underlying statutory scheme. *Id.* (to state a FCA claim it is necessary "to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but also that payment of the federal funds was in some way conditioned on compliance with those regulations," otherwise the FCA is a "'blunt instrument to enforce compliance with all . . .

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[17] *See, e.g.*, *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (discussing "fraud in the inducement" cases arising "when the contract or extension of government benefit was obtained originally through false statements or fraudulent conduct"); *United States v. Ehrlich*, 643 F.2d 634 (9th Cir. 1981) (false negotiation, including bid rigging and defective pricing); *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977) (discussing false certification of compliance with federal law); and *United States v. Aerodex, Inc.*, 469 F.2d 1003 (5th Cir. 1972) (FCA liability for supplying substandard products or services).

regulations' rather than 'only those regulations that are a precondition to payment.'"); *Wilkins*, 2010 WL 1931134, at *3 (under certification theories, payment must be conditioned on compliance with statute or regulation).

As such, Relator's "fraudulent claims" theory is logically and legally indistinguishable from the "implied certification" theory. Both theories hold that claims that are not facially false may be rendered actionable where an independent rule provides that items will not be eligible for reimbursement if they are supplied in a manner violative of a regulatory scheme. The "fraudulent conduct" theory is therefore just the "implied certification" theory in different guise and it is subject to all of the objections applicable to the "implied certification" theory set forth above. *Supra* 10-11; *see generally, United States ex rel. Gonzalez v. Fresenius Med. Care N.A.*, 2010 WL 1645971 , at *11-15 (W.D. Tex. Mar. 31, 2010) (analyzing "per se tainted" theory, involving allegation of fraudulent course of conduct, and implied certification, and finding both were unsupported in the Fifth Circuit).

b. The Complaint Fails To Allege Adequately That Off Label Marketing Constitutes "Fraudulent" Conduct.

In any event, though the SAC alleges in broad strokes that Genentech unlawfully "marketed" Rituxan, it does not allege that the company *fraudulently* violated the FDCA. As such, it does not allege the necessary predicate act for Count I.

As a starting point, violations of the FDCA can be either strict liability misdemeanors or felonies, with culpability for the latter predicated on proof of "intent to defraud or mislead." 21 U.S.C. § 333(a). "Fraud," of course, means "[a] knowing false representation[] of material fact." *Zurawski v. Se. Pa. Transp. Auth.*, 2010 WL 1946922, at *6 (E.D. Pa. May 10, 2010). In light of this, it is well established that unlawful off-label "marketing" can involve *either* fraudulent or *non*-fraudulent conduct. *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 n.6 (N.D.

Cal. 2009) ("off-label marketing of an approved drug is itself not inherently fraudulent").[18] Indeed, several courts have held that allegations based on non-fraudulent "off label" promotion are insufficient to support claims of fraud, including in the FCA context. *United States ex rel. Polansky v. Pfizer*, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009) ("the mere fact that Pfizer may have been violating FDA regulations does not translate into liability for causing a false claim to be filed"); *United States ex rel. Rost v. Pfizer*, 253 F.R.D. 11, 16-17 (D. Mass. 2008) ("Merely alleging off-label marketing, a criminal act, is not sufficient, without more, to plead a false claims act violation."); *In re Schering-Plough Corp*., 2010 WL 2346624, at *8 n.6 (dismissing civil RICO complaint predicated on alleged off-label promotions, and stating that "[o]ff-label promotion may run afoul of the FDCA, but it does not by itself necessarily constitute fraudulent conduct.").

Here, the SAC does not allege "fraud" – it does not allege that Genentech falsely represented any fact about Rituxan to physicians (or anyone else). *Compare Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 891-92 (N.D. Cal. 2009) (relator alleged that defendant lied to doctors about medical studies). In fact, after reviewing the voluminous discovery provided by the Government, Relator elected to *excise* all of his earlier allegations to the effect that Genentech made false statements to physicians. The SAC manifestly does not allege a

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[18] *See also In re Epogen & Aranesp Off-Label Mktg. & Sales Prac. Litig*., 590 F. Supp. 2d 1282, 1289 (C.D. Cal. 2008) (allegations did not support charge of wire fraud when the "main thrust of [plaintiffs'] allegations is that Defendants illegally promoted [the drug] for off-label uses, *not* that Defendants promoted [the drug] through false, misleading, or otherwise fraudulent statements"); *United States v. Caronia*, 576 F. Supp. 2d 385, 397 (E.D.N.Y. 2008) (alleged promotion "of the off-label uses of a FDA-approved drug concerns lawful activity and is not inherently misleading").

"fraudulent" violation of the FDCA and therefore cannot sustain a claim under the "fraudulent" prong of the FCA.[19]

Were there any doubt about this conclusion, the Court would be compelled by the doctrine of "constitutional avoidance" to construe the SAC so as to avoid creating liability. Under the terms of that doctrine, courts should, if possible, avoid interpretations of statutes that raise constitutional concerns. *See, e.g., Commodities Futures Trading Comm'n v. Schor,* 478 U.S. 833, 841 (1986) (the doctrine of constitutional avoidance provides that "[f]ederal statutes are to be construed so as to avoid serious doubt of their constitutionality") (citing *Machinists v. Street*, 367 U.S. 740, 749 (1961)).

Here, the complaint alleges a violation of law based on *truthful* speech. Speech about matters of scientific importance is entitled to full constitutional protection, *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998) ("[s]cientific speech . . . reside[s] at the core of the First Amendment"), *vacated sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000), even if mixed with "commercial" speech, *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988) (commercial speech that "is inextricably intertwined with otherwise fully protected speech" is entitled to full First Amendment protections). But even if Genentech's speech were deemed entirely "commercial," it would nonetheless enjoy substantial

[19] Indeed, the SAC does not specifically allege *any* statutory violation. It refers broadly to illegal "marketing" and "promotion," but the FDCA does not make either of those specific activities unlawful. To be sure, the Act does prohibit certain forms of communication about off-label uses (e.g., "false and misleading" statements, 21 U.S.C. § 352(a)), but the Act's prohibitions are nuanced, and the regulatory scheme and agency guidances implementing the Act affirmatively *authorize* manufacturers to disseminate certain off-label information in the form of "scientific exchange" (21 C.F.R. § 312.7), reprints (*Reprints Guidance*, *available at* http://www.fda.gov/oc/op/goodreprint.html), and in response to unsolicited requests for information, (*see id.* at n.5). Manufacturers are also authorized to provide financial support for Continuing Medical Education on off-label topics (62 Fed. Reg. 6407 (Dec. 3, 1997). By failing to distinguish the lawful from the unlawful, Relator does not state *any* legal violation.

protection under the First Amendment and could not be restricted absent a showing that the restriction (here, the FCA) directly advances a substantial government interest and is no more extensive than necessary. *See, e.g., Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980) (establishing test); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002) (rejecting "the notion that the Government has an interest in preventing the dissemination of truthful commercial information" and invalidating FDA's regulations pursuant to intermediate scrutiny under the *Central Hudson* standard). Thus, under these circumstances, the Court should *not* readily infer from Relator's non-specific allegations that the underlying alleged violation of the FDCA was "fraudulent" and hence actionable. Instead, it should interpret the SAC not to allege fraud, and thereby avoid the substantial constitutional question of whether the penalties under the FCA are an appropriately tailored means of sanctioning Genentech's truthful speech.

B. The Complaint Does Not Adequately Allege That Genentech "Caused" Any False or Fraudulent Claims To Be Submitted.

Even if claims submitted for off-label uses of Rituxan were "false" or "fraudulent," Relator has also failed adequately to allege that Genentech "caused" physicians to submit them. That defect independently renders Count I of the SAC deficient under Rule 12(b)(6). *See, e.g., City of Phila. v. Beretta U.S.A. Corp.*, 277 F.3d 415, 423 (3d Cir. 2002) (affirming dismissal under Rule 12(b)(6) of complaint that failed adequately to allege causation).

To determine causation under the FCA, the Third Circuit applies general tort principles. *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004). The test in the Third Circuit is essentially one for proximate causation. *Beretta*, 277 F.3d at 423 (identifying relevant factors). Thus, a relator must allege facts sufficient to establish that the defendant's conduct was a “substantial factor” in false claims being submitted to the government. *Zimmer*, 386 F.3d at 244-45.

As a matter of law, causation was not and cannot be met in this case. First, on its face, the SAC notably does not allege that Genentech’s sales representatives (or any other employees) caused physicians to submit false claims. The SAC alleges that Genentech *internally* discussed promoting Rituxan for off-label purposes (SAC ¶¶ 29, 31-42, 44-47), that physicians resisted prescribing for off-label purposes (SAC ¶ 43), that physicians and providers encountered “difficulty” when seeking reimbursement for off-label uses, (SAC ¶ 48, 50-52), and that Genentech offered to help physicians appeal from reimbursement denials, (SAC ¶ 49). But at no point does the SAC contain *any* allegation that sales representatives (or anyone else) actually promoted Rituxan off-label to physicians. Therefore, the SAC does not allege the required “causal” connection linking Genentech’s alleged internal communications to the actual submission of claims (false or otherwise) by physicians. This deficiency is not cured by the inference that many claims *must* have been submitted, as the mere volume of prescriptions for off-label indications does not, as a matter of law, establish causation. *See, e.g., In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2010 WL 2346624, at *9 (D.N.J. June 9, 2010).

But the core problem here is revealed not by Relator’s failure to allege an element of the FCA, but rather by an allegation he did make: that doctors “were reluctant to prescribe Rituxan … without the evidence provided by significant clinical trials” (SAC ¶ 43). This allegation acknowledges a key, and insurmountable, legal obstacle –that physicians are presumed to exercise their independent medical judgment to treat their patients. *See Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1355-56 (3d Cir. 1992) (“‘“[i]t is for the prescribing physician to use his independent judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug"'") (alteration in original). This presumption is embodied in the rule that physicians are "learned intermediaries" and, as such, cut off the chain of causation between a manufacturer's actions and their potentially foreseeable consequences. *See Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007) (discussing Pennsylvania's learned intermediary doctrine); *cf. Labeling Requirements for Systemic Antibacteria Drug Products Intended for Human Use*, 68 Fed. Reg. 6062, 6071 (Feb. 6, 2003) ("The physician is then responsible for making the final judgment as to which, if any, of the available drugs his patient will receive in light of the information contained in their labeling *and other adequate scientific data available to him.*") (emphasis added).[20] In short, because physicians, as learned intermediaries, are presumed to make independent professional decisions based on all the published literature and other information available to them, Relator cannot establish that Genentech *caused* physicians to submit off-label claims, and Count I fails.

This rule has been applied in at least one other case. In *Polansky*, the relator contended that Pfizer's alleged off-label marketing of Lipitor caused physicians to prescribe it for patients with "normal" cholesterol levels. The district court dismissed the complaint on Rule 9(b) grounds, holding that the relator could not even *plead* causation. Specifically, taking judicial notice of the fact that, during the time frame in which Pfizer was allegedly unlawfully promoting its product, there were numerous published reports by heart disease experts advising patients to lower LDL cholesterol levels below the national guidelines, the court concluded that "against the backdrop of the clinical trials and studies discussed above, as well as the tenuous theory underlying his FCA cause of action . . . Dr. Polansky [had] not strengthen[ed] the inference of fraud beyond possibility." *Polansky*, 2009 WL 1456582, at *10 (quotation omitted).[21]

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[20] The legal rule that physicians are presumed to make independent medical judgments has particular force in the field of oncology, where physicians – along with their patients – make life-and-death decisions. For this reason, this Court should not lightly presume, based on Relator's general allegations, that Genentech "caused" oncologists across the country to make judgments that were not, in fact, independent. Among the many factors that may have influenced oncologists to prescribe Rituxan for uses outside of its original label before FDA approved those uses, is the fact that the National Cancer Institute identified Rituxan-related therapies as standard treatment options for frontline indolent NHL, frontline aggressive NHL, and CLL before the FDA approved the drug for those uses. http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/HealthProfessional/page7. Similarly, the National Comprehensive Cancer Network recognized Rixan as the standard of care for numerous disease states well prior to FDA approval. NCCN Suggested Treatment Regimens (2005).

Finally, even if physicians were not legally presumed to act independently, the SAC still fails adequately to allege "causation." Physicians are lawfully entitled to (and frequently do) prescribe drugs off-label. It is therefore just as "foreseeable" that physicians exposed to Genentech's allegedly unlawful messaging would have submitted off-label claims for reimbursement based on their own judgment as they would based on the company's marketing message. The obligation to plead the causation element requires a relator to distinguish between these two foreseeable consequences. Relator has not done so, and the SAC fails for this additional reason as well.[22]

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[21] *See also Ironworkers Local Union No. 68 & Participating Employers Health & Welfare Funds v. AstraZeneca Pharms. L.P.*, 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008) (dismissing civil RICO action because plaintiffs could not establish a "direct relation" between the conduct alleged and the purported injury, holding that "[p]resumably, these physicians use their independent medical judgment to decide whether [the drug] is the best treatment for a given patient. This independent judgment can be influenced by a number of things, only one of which may be representations by a manufacturer . . . ."); *In re Actimmune*, 614 F. Supp. 2d at 1055 ("The issue is whether the studies themselves could have provided another basis for physician reliance, apart from the allegedly misleading representations . . . . Plaintiffs fail to address this possibility and therefore fail to sufficiently allege that the purportedly fraudulent practices of defendants fostered a belief that Actimmune was effective [for treating an off-label disease], resulting in plaintiffs' harm").

C. Genentech's Alleged Conduct Was Not Material To Any Payment Decision.

In addition to the express statutory requirements of the FCA, "[l]iability under each of the provisions of the [Act] is subject to the further, judicially-imposed, requirement that the false statement or claim be material." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999). In this context, "materiality" refers to whether the alleged misconduct is capable of influencing the Government's decision to pay the claim.[23] Complaints that fail to allege materiality should be dismissed. *United States ex rel. Lobel v. Express Scripts, Inc.*, 2008 WL 5083115, at *2 (E.D. Pa. Dec. 1, 2008) (dismissing FCA complaint for, among other reasons, failing to allege that the cited regulatory violation was material to the government's decision to pay the claims), *aff'd*, 351 F. App'x 778 (3d Cir. 2009).

Here, Relator does not allege that Genentech's alleged "off-label marketing" was "material" to the Government's reimbursement decisions – *i.e.*, that the Government would not have paid the claims at issue had it "known" that Genentech had marketed the drug for off-label uses. That alone warrants dismissal of Count I. In any event, he could not have done so. As a general matter there is no law authorizing the Government to withhold payment from physicians based on the conduct of drug manufacturers. *See supra* 10-11.

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[22] The Third Circuit has also identified "the aim of keeping the scope of complex trials within judicially manageable limits" as one of the important common-law factors to be considered in determining whether causation exists. *Beretta*, 277 F.3d at 423 (citing as one of the six elements to a causation analysis the). Absent much greater detail about causation, this factor has plainly not been satisfied as it would require an enormous amount of physician-by-physician and claim-by-claim discovery to tease out the valid from the invalid off-label claims for reimbursement.

[23] Although the Third Circuit has assumed, without expressly deciding, that materiality is an element of a FCA violation, every other court of appeals has held that materiality is an element of a FCA claim. *See Harrison*, 176 F.3d at 785; *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 679 n. 3 (5th Cir. 2003) (en banc) (Jones, J. concurring); *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 442 (6th Cir. 2005); *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999); *United States ex rel. Costner v. United States*, 317 F.3d 883, 886 (8th Cir. 2003); *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1172-73 (9th Cir. 2006); *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1219-20 (10th Cir. 2008); *United States v. TDC Mgmt. Corp.*, 24 F.3d 292, 297 (D.C. Cir. 1994); *United States ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402, 415 (3d Cir. 1999).

In addition, at least one court has made clear that, as a matter of law, an issue is not "material" to a payment decision if the Government does not ask about it. In *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006), the relator alleged that the defendant marketed a cancer drug approved as a second-line therapy for an off-label use (as a first-line therapy). The district court dismissed the case for failure to state a claim under Rule 12(b)(6) because the reimbursement form did not seek information about the stage of cancer. *Id.; see also, United States ex rel Stephens v. Tissue Sci. Labs., Inc.*, 664 F. Supp. 2d 1310, 1318-19 (N.D. Ga. 2009) (dismissing off-label FCA claim pursuant to Rule 12(b)(6) on materiality grounds where the alleged conduct was not capable of affecting payment decisions).

The logic of the *Hess* case mandates dismissal here. The 1500 Form used for Rituxan simply asks for the patient's diagnosis (at a high level of generality) and treatment. *See* Decl. Welsh, Ex. B. It does not seek information about whether the treatment is for "front-line" or "recurrent" disease, and it does not seek information about the dosing regimen (e.g., "maintenance"). Accordingly, the line of therapy and dosing regimens were legally immaterial to the Government's reimbursement decisions. And, to the extent that the Government knowingly decided to reimburse for patients who were openly and correctly identified on the 1500 Form as having CLL, Rheumatoid Arthritis, Idiopathic Trombocytopenic Purpura, Autoimmune Hemolytic Anemia, Pure Red Cell Aplasia, and Systemic Lupus Erythematosus, then the fact that those patients were being treated off-label manifestly was not material either. *See Rost*, 253 F.R.D. at 16 (D. Mass. 2008) (a state's knowing decision to reimburse for a drug for an off-label use would negate intent as a matter of law). For that independent reason, Count I must be dismissed.

II. COUNT II SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM.

Count II of the Complaint also should be dismissed because Relator's "Advisory Board" allegations fail to state any claim under the FCA. Relator alleges that Genentech invited physicians to participate in "Advisory Boards" (*i.e.*, panels of experts convened to advise the company on various matters) and that this conduct violated the AKS. (SAC ¶ 62.) Relator alleges that "[e]ach claim for reimbursement for *any* use of Rituxan, submitted to Medicare by any physician after having accepted an invitation to an 'advisory board meeting' was fraudulent in that it was caused, in part at least, by Genentech's violation of the Anti-Kickback Statute." (*Id.* ¶ 61 (emphasis added).) This conclusory allegation fails to support any claim under the FCA for two reasons.

First, the allegation that Genentech paid honoraria to physicians and provided expenses-paid trips to meetings does not establish a violation of the AKS. "Labeling such remunerations and gifts as bribes appears in large part to amount to a legal conclusion, especially given the absence of details regarding specific instances of payment." *In re Schering-Plough Corp.*, 2010 WL 2346624, at *10 (dismissing RICO claims predicated on alleged off-label promotional activity in violation of FDCA). Indeed, the Court should be particularly wary of allowing Count II to proceed based solely on Relator's characterizations given Relator's failure to address the applicability of the AKS "safe harbors." To address the overbreadth of the plain language of the AKS, the Office of Inspector General of the Department of Health & Human Services has established by regulation a number of “safe harbors” for certain kinds of arrangements that will not be deemed to be unlawful “remuneration.” Relevant here is the safe harbor for “personal services,” which exempts from AKS liability payments and other remuneration made as compensation for services provided at fair market value. 42 C.F.R. § 1001.952(d). Therefore, Relator’s conclusory allegations that Genentech reimbursed doctors (even “lavishly”) in connection with their service on Advisory Boards fails to establish that Genentech paid “unlawful remuneration.”[24]

Second, and more importantly, merely alleging that Genentech violated the AKS does not support the conclusion that it caused any “false or fraudulent claims” to be submitted. Relator does not allege that Genentech’s alleged violation of the AKS rendered any claim “factually false.” He also does not allege – nor could he – that Genentech, or any of the physicians who participated in Advisory Boards and submitted claims for reimbursement, made a false express certification of compliance with the AKS. As noted, the 1500 Form, on which physicians submit claims to Medicare, requires an express certification that the services were medically necessary but notably does not require a certification of compliance with the AKS or all laws generally. *Supra* at 21.

This leaves only the possibility of an “implied certification”/“fraudulent claims” theory. But as noted above, the Third Circuit pointedly has declined to adopt this theory of liability.

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[24] Similarly, Relator’s allegation that “Genentech rewarded its highest-scoring sales people with an invitation to an Advisory Board meeting” (SAC ¶ 59) does not establish any violation of the AKS because the employee safe harbor expressly excludes Genentech’s compensation to its own employees from the scope of the AKS. *See* 42 C.F.R. §1001.952(i) (“‘remuneration’ does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs”).

Supra 10-13, *see Our Lady of Lourdes Med. Ctr.*, 552 F.3d at 304. Moreover, neither the "implied certification" theory nor its twin "fraudulent claims" theory can transform a violation of the AKS into an actionable predicate for a FCA claim.[25] As set forth above,

> [t]o state a claim under [an implied certification] theory it is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but *also that payment of the federal funds was in some way conditioned on compliance with those regulations*. . . . Otherwise, the False Claims Act would be turned into a 'blunt instrument to enforce compliance with all . . . regulations' rather than 'only those regulations that are a precondition to payment.'

Id. (internal citations omitted) (emphasis added) (omission in original).

Where Congress intends compliance with a particular statute to be a precondition to payment, it has expressly said so. For example, the "Stark" law, which restricts the ability of providers to make referrals to entities in which they have an ownership interest, expressly states that that "[n]o payment may be made under this subchapter for a designated health service which is provided in violation of [the prohibition on self-referrals]." 42 U.S.C. § 1395nn(g)(1). Here, the SAC does not allege that compliance with AKS was a condition of payment of claims for reimbursement for cancer drugs submitted by physicians, and it could not do so as the AKS contains no such language. Therefore, merely alleging that a defendant violated the AKS, as relator has done here, is not sufficient to state a FCA claim.

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[25] In an opinion issued three weeks after *Our Lady of Lourdes Medical Center*, another panel of the Third Circuit stated in dicta that that "[f]alsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA." *United States ex rel. Kosenske v. Carlisle HMA, Inc*., 554 F.3d 88, 94 (3d Cir. 2009). Notably, the Court did not acknowledge *Lourdes*. Furthermore, the court's statement plainly is *dicta*, as the only issue on appeal was whether the relator had presented sufficient evidence of a violation of the Stark law (which *does* state that claims submitted in violation of the law are false) to survive summary judgment. The Court expressly noted that whether that violation established a violation of the FCA had not been decided. *Id.* at 98-99 n.3. The only Third Circuit case cited by the *Kosenske* court was *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004), in which the court assumed (without deciding) that the relator could pursue a FCA claim premised on alleged violations of express false certifications by hospitals.

Relator's failure to allege a connection between the alleged "kickbacks" and a violation of the FCA warrants dismissal. Thus, for example, in *United States ex rel. Westmoreland v. Amgen, Inc.*, 2010 WL 1634315 (D. Mass. Apr. 23, 2010), the relator asserted FCA claims against a pharmaceutical manufacturer that allegedly paid "kickbacks" to physicians, under an implied false certification theory. The district court rejected the argument that the alleged kickbacks rendered the physicians' claims "false or fraudulent" and dismissed the case pursuant to Rule 12(b)(6):

> Defendants correctly state that no statute or regulation expressly requires compliance with anti-kickback statutes as a condition of payment. . . . The only shaft left in Relator's quiver is the enrollment agreement, but this Court has held that in the context of implied certification, "a precondition [of payment] cannot be hidden in an enrollment form.

Id. at *11.[26] *See also Wilkins*, 2010 WL 1931134, at *6 (holding that implied certification is viable only when the underlying statute *expressly* states that payment is conditioned on compliance).

Beyond these deficiencies, Relator also fails to allege other essential elements of a FCA claim. For example, he fails to allege how the mere fact of a physician "having accepted an invitation to an advisory board meeting" somehow "caused" the submission of a false claim (SAC ¶ 61) – *i.e.*, the SAC fails to "'spell out' [the] connection between [the] alleged regulatory violation and receipt of Government funds." *Wilkins*, 2010 WL 1931134, at *5 (citing *Our Lady*

[26] The court went on to explain that while some cases have stated that "Medicare providers impliedly certify compliance with the anti-kickback statute, [they] either do not explain why they so hold, involve parties who agree that failure to comply with anti-kickback statutes can be the basis of the implied certification theory, or conflate the implied certification theory with a materiality analysis." *Id.*

of Lourdes Med. Ctr). Accordingly, Count II should be dismissed pursuant to Rule 12(b)(6) for failure to plead any FCA claim premised on alleged violations of the AKS.

III. BOTH COUNTS SHOULD BE DISMISSED FOR FAILURE TO PLEAD WITH THE PARTICULARITY REQUIRED BY RULE 9(b).

The Court denied Genentech's motion to dismiss the First Amended Complaint ("FAC") under Rule 9(b), holding that though Relator had not identified any specific false claims, he had satisfied his obligation to "'use an alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud,'" thus placing Genentech "'on notice of the precise misconduct with which [it is] charged.'" Mem. Order at 14 (June 2, 2010) (Doc. 77) (Order). In light of both the substantial differences between the FAC and the SAC, and the fact that the SAC does *not* allege the "precise misconduct with which Genentech is charged," the SAC should be dismissed on the alternative ground that it fails to satisfy Rule 9(b).[27]

As a starting point, the SAC, like its predecessor, does not allege with particularity any specific false claim, and thus should be dismissed for this reason alone. *See United States ex rel. Sanders v. American-Amiable Life Ins. Co. of Texas,* 545 F.3d 256, 258-59 (3d Cir. 2008) (a relator must plead with particularity both the underlying fraudulent conduct *and* the submission of "false claims"). In its ruling on Genentech's Motion to Dismiss the FAC, the Court rejected this argument, reasoning that, as a corporate insider, "Relator [could not] reasonably could be required to identify at the pleading stage a specific false claim submitted to the Government by a third party (perhaps doctors or a pharmacy)." Order at 14. Though the company disagrees with that reasoning, it highlights the fact that Relator should certainly *not* be relieved of his obligation to allege the underlying *corporate* fraud in detail. He has plainly failed to do that.

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[27] Genentech incorporates by reference the arguments its advanced in its Motion to Dismiss the [First] Amended Complaint Pursuant to Rule 9(b) (May 11, 2101) (Doc. 73).

Specifically, the SAC does not allege the "who, what, when, where, and how" of either Genentech's alleged FDCA violation or the AKS violation. *See Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242. 253 (3d Cir. 2009) (Rule 9(b) "'requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story'"); *Zimmer*, 386 F. 3d at 242 n. 9. Nor does the SAC "use an alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud." Order at 14 (quoting *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998) (quotation omitted)). Indeed, with respect to the alleged FDCA violation, the SAC *does not allege "fraud" at all*, as it does not allege that Genentech made any untruthful statement, much less with the intent to defraud or mislead. Nor does it allege what statutory provisions the company allegedly violated; how Genentech's internal communications "caused" physicians to submit unlawful claims, how Genentech's conduct was "material" to any Government reimbursement decision;[28] or – fundamentally – how off-label claims submitted by physicians for Rituxan were "false or fraudulent." In particular, Relator's new allegation (SAC ¶ 29) that Genentech marketed Rituxan off-label to treat Rheumatoid Arthritis, an indication for which it received approval in 2006**,** is utterly devoid of support. The only reference in the SAC to that disease is the phrase "Rheumatoid Arthritis" appended to paragraph 29; no other detail whatsoever is provided. Likewise, Count II contains no details about the physicians involved in the alleged kickback scheme, what they were paid or for what services rendered, how they were unlawfully influenced, or what "false or fraudulent" claims they submitted. None of these deficiencies with respect to either count is salvaged by the boilerplate legal conclusions in paragraphs 55 and 62 of the SAC that "as the direct, proximate and foreseeable result of Genentech's fraudulent course of conduct, … Genetech caused tens of thousands of fraudulent claims to be submitted." *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); (Rule 8(a) requires well-pleaded facts that support the claim, not "'labels and conclusions'" or "'a formulaic recitation of the elements of a cause of action'"); *Fowler*, 578 F.3d at 210-11 (courts are obligated to disregard legal conclusions when evaluating complaint).

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[28] *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007) (dismissing FCA claim on 9(b) grounds because, *inter alia*, "It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients."), *overruled on other grounds as recognized in United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13 (1st Cir. 2009).

CONCLUSION

WHEREFORE, Genentech respectfully requests that the Court dismiss the Complaint with prejudice.

Date: June 23, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Robert E. Welsh, Jr., do hereby certify that on this date I caused a true and correct copy of the foregoing document to be served upon the following counsel via electronic mail:

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Robert E. Welsh, Jr.

Date: June 23, 2010